

*Imagine your
tremor free life!*

Neuravive™

Non-Invasive
Treatment for
Essential Tremor

The non-invasive treatment for Essential Tremor (ET) is performed using Neuravive.

— WHAT IS ESSENTIAL TREMOR?

Essential Tremor (ET) is a neurological condition that causes shaking of the hands, head and voice, but it can also cause legs and trunk to shake. Some people even have a feeling of internal tremor. Essential Tremor is the most common movement disorder affecting as many as 41 million patients worldwide.¹

The cause of essential tremor is still not fully understood, but years of previous surgical work has identified the Vim nucleus of the thalamus in the brain, which can be treated to alleviate the tremor. The thalamus is a structure deep in the brain that coordinates and controls muscle activity.

SYMPTOMS

The primary symptoms associated with essential tremor include:

- Uncontrollable shaking that occurs for brief periods of time
- Begins gradually, usually on one side of the body
- Occurs in the hands first, affecting one hand or both
- Can include a shaking voice or tremor of the head
- Nodding head
- Worsening during periods of emotional stress and purposeful movement
- Balance problems (in rare cases)

¹<http://www.londonmdc.ca/research/tremor.html>



+ WHAT IS THE NEURAVIVE TREATMENT?

Neuravive is a non-invasive treatment that reduces tremor. It is based on MR-guided Focused Ultrasound (MRgFUS) technology which combines high intensity focused ultrasound that is guided by Magnetic Resonance Imaging (MRI).

Ultrasound is a form of energy that passes through skin, muscle, fat and bone. Ultrasound energy is non-ionizing, meaning the patient is not being exposed to radiation during the procedure. High intensity focused ultrasound energy, when focused on a small target volume, raises the tissue temperature of the target high enough to destroy it, thereby providing a therapeutic effect.

During the Neuravive procedure, ultrasound waves pass through the brain without a need for an incision. These ultrasound waves are focused on a specific point in the brain (Vim of the thalamus) to create a tiny ablation or burn.

The whole procedure is conducted inside the imaging scanner. The MRI is the eyes of the treatment, enabling the physician to plan, guide and target the area easily. It also enables precise measurement of the temperature in order to verify that only the intended tissue is targeted and destroyed.

From FDA labeling: Exablate Neuro is intended for use in the unilateral thalamotomy treatment of idiopathic Essential Tremor patients with medication-refractory tremor. Patients must be at least age 22.

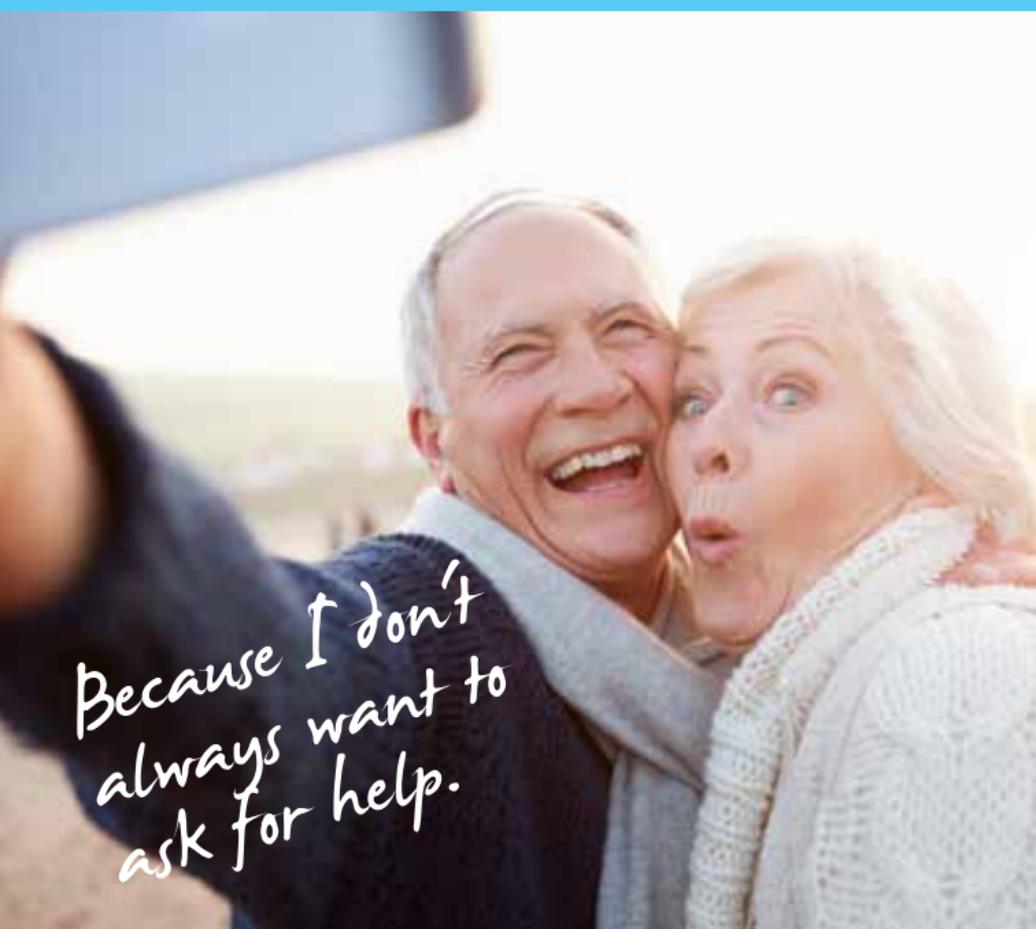
+ NEURAVIVE: TREATMENT BENEFITS

- **TREMOR IMPROVEMENT** – In clinical studies, patients reported an immediate and significant improvement in tremor.²
- **NON-INVASIVE** – The focused ultrasound treatment is capable of penetrating the skull without making an incision.
- **QUICK RECOVERY** – Since the treatment is non-invasive, it can be performed as an outpatient procedure, meaning minimal hospitalization is needed. You can expect to resume normal activities within days.
- **FDA APPROVED** - Safe and effective with minimal side effects.²



+ ESPECIALLY IMPORTANT TO SHARE WITH YOUR DOCTOR

It is extremely important to discuss all medical conditions with your physician so your suitability for the procedure can be properly evaluated.



*Because I don't
always want to
ask for help.*

²<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm510521.htm>

REPORTED FROM THE PIVOTAL CLINICAL STUDY:

Elias WJ, Lipsman N, Ondo WG, Ghanouni P, Kim YG, Lee W, Schwartz M, Hynynen K, Lozano AM, Shah B, Huss D, Dallapiazza RF, Gwinn R, Witt J, Ro S, Eisenberg HM, Fishman PS, Gandhi D, Halpern CH, Chuang R, Butts Pauly K, Tierney TS, Hayes MT, Cosgrove GR, Yamaguchi T, Abe K, Taira T, Chang JW. , An International, Randomized, Controlled Trial of Focused Ultrasound Thalamotomy for Essential Tremor. The New England Journal of Medicine, Aug 2016.

+ IS THE NEURAVIVE TREATMENT AN OPTION FOR ME?

The Neuravive treatment is intended for Essential Tremor patients who are at least 22 and have not responded to medication. It is important to consult with your physician to determine if the Neuravive treatment is right for you.

As part of the evaluation process, your physician will need to determine the severity of your tremor and perform a full medical evaluation to assess your overall condition. This is necessary to ensure a safe and effective Neuravive treatment for your condition.

Patients will also need to undergo a CT scan in order to verify that Neuravive is suitable for them.

Patients should be aware that the entire procedure is fully conducted inside an MRI scanner which takes images to help the doctor identify the proper location, verify the effect and complete the final treatment. The patient is awake, because it is necessary to receive patient feedback during the procedure.

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm510521.htm>

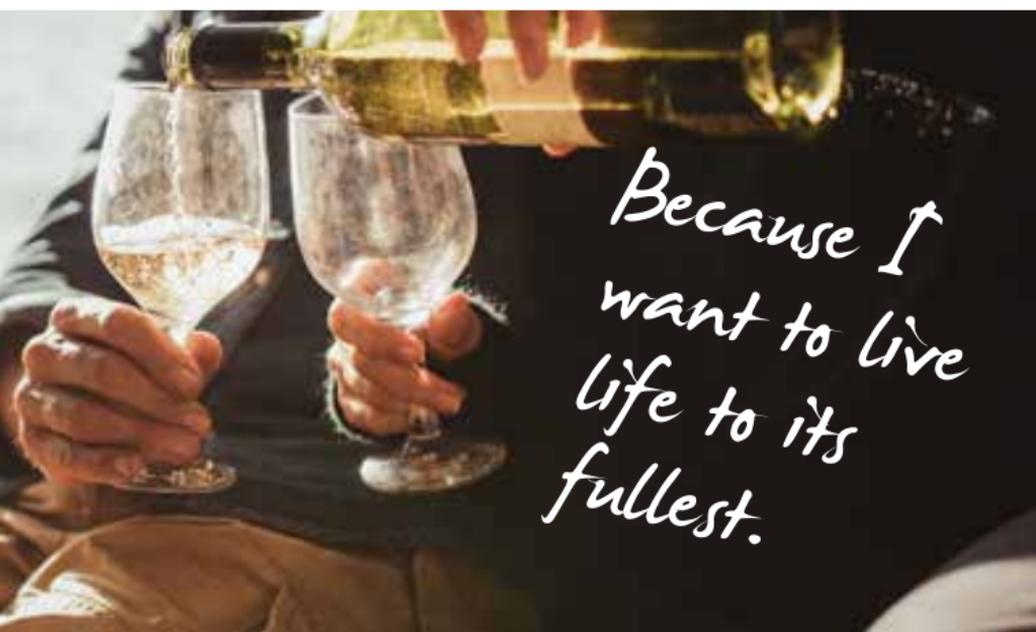


If you have metallic implants such as pacemakers, neuro-stimulators, spine or bone fixation devices, total joints, metal clips, screws, etc. you will need to consult with your doctor to see if Neuravive is an option for you. Any metallic implants must be MRI safe to prevent injury to the patient from the MRI's strong magnetic field.

Also, if you are not generally healthy enough to withstand the treatment and lie still in the same position for approximately 3 hours you should consult with your doctor as you may not be a good candidate for this treatment.

In addition, if you suffer from any of the following, you may not be a good candidate for this procedure:

- Extensive scarring on the scalp
- If you are pregnant
- Tumors inside the skull
- Heart conditions
- Receiving dialysis
- Have an active infection
- Severe hematological, neurological or other uncontrolled disease



+ WHAT HAPPENS BEFORE, DURING AND AFTER THE TREATMENT?

Preparation: The scalp will be shaved and cleaned. You will be given a local numbing medication and an immobilizing frame will be secured to your head. You will have a urinary catheter placed to drain your bladder during the procedure, so you won't have to go to the bathroom. Your heart rate, blood pressure and blood oxygen levels will be monitored throughout the procedure. You will then lie on the treatment bed which will move in and out of the MRI system. You may be given additional medication to keep you comfortable. You will be conscious, communicating with the physician and nurses throughout the treatment.

Planning: First, a series of MRI images will be taken for the purpose of planning the treatment. The physician will mark the area to be treated on the Neuravive software and light doses of ultrasound energy will be administered in order to ensure the proper spot in the brain has been located.

Cool water will circulate in the helmet around the top of your head and you will be kept warm in case you get chilled. You will also be given a "stop sonication" button to indicate to the physician that you want to stop the procedure for any reason.

Treatment: During treatment, the physician will ask you questions and have you perform tasks in order to confirm the accuracy of the target. Certain tasks may include touching your nose with your finger and/or drawing circles on a board. Once your physician is confident of the proper location, the focused ultrasound will be used to make the permanent burn of that location. The treatment will last between 3-4 hours from when you get on the treatment table until you get off.



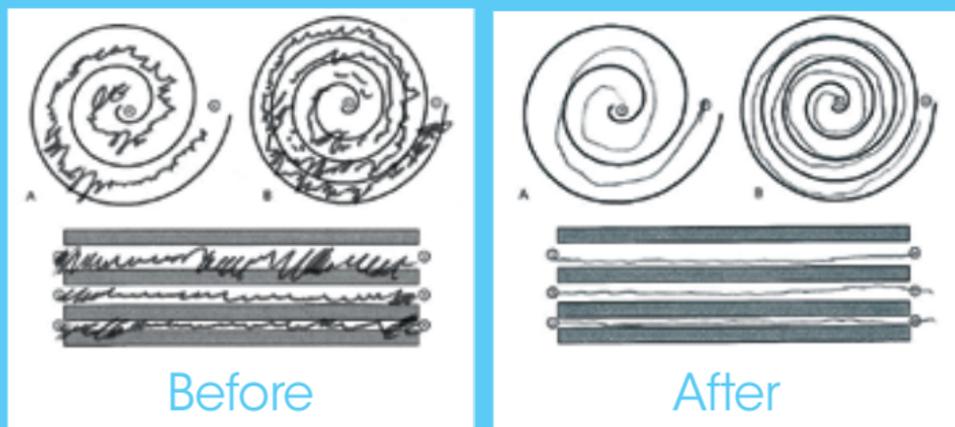
Post Treatment: After treatment, you will move to the recovery room for observation. The frame will be removed from your head. You will rest up to 24 hours in the hospital or clinic and at some point have a final 20 minute MRI scan for post treatment assessment.

Your physician will let you know when you will need to return for any follow-up visit.

+ WHAT RESULTS CAN I EXPECT?

Patients who have undergone this procedure have shown a significant reduction in tremor, resulting in improvement in performing daily activities such as, eating, drinking and writing.²

DRAWING TEST



Individual results may vary.



+ NEURAVIVE: RISKS & SIDE EFFECTS

Be sure to discuss with your physician all the risks involved with the Neuravive treatment. In general, the side effects of the Neuravive treatment are minimal, but as with any medical procedure, there are risks:

- For short periods of time during the treatment you may experience dizziness, pain or other sensations.
- There is the possibility that your tremor may return some months or years after treatment.
- There is a small risk that you could develop temporary or permanent muscle weakness, imbalance, and/or gait disturbance, sensory effects (tingling, numbness) in your fingers or elsewhere in your body.
- It is possible that your tremor may not improve.
- This procedure does not treat the underlying disease nor prevent the progression of the disease.



I always loved baking, so I decided to open my own bakery.

One day, my right hand started to shake.

Gradually I couldn't do daily activities like drink or eat, not to mention baking or serving coffee to my customers. I became completely dependent on my staff.

The doctors prescribed drugs, but they didn't work for me.

One day they suggested the MRI guided focused ultrasound procedure.

I knew I would have to shave my head, but I just wanted to live my dream - to serve my customers again.

After a couple of hours or so, on the MRI bed, my hand didn't shake anymore.

Haya Mendlebaum, Neuravive Patient



Disclaimer: Patient testimonials may not be representative of all treatment outcomes.



Neuravive™

Visit our website for more information about the
Focused Ultrasound treatment for Essential Tremor:

www.essential-tremor.com

For more details:

[http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/
DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm510521.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm510521.htm)

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Device name: Exablate Neuro